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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,992	04/05/2001	Nurhan Pinar Tutuncu	2280.2660	3697
5514	7590	02/17/2004	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/825,992	TUTUNCU ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Amendment to claims received on October 30, 2003 is acknowledged.

Claims **1-8 and 10-24** are pending in this application. Claim 9 stands cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1-8, 10-16 and 23-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not provided support for more than one region of a salivating region and oral comforting region respectively. A careful examination of the specification only shows support for one salivating region and one oral comforting region.

Response to Arguments

Applicant argues that page 16, lines 16-32 discloses at least two separate and distinct regions".

Applicant's arguments have been fully considered but they are not persuasive. Firstly, it is pointed out that the examiner has not disputed the assertion that the invention contains more than one region, the rejection is made on the basis that

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applicant has amended the claims to recite that there are more than one salivation regions and oral comforting regions respectfully. The cited page 16 of the instant specification supports the assertion of one oral comforting region, one salivation region, and one region that does not contain either an oral comfort or salivation ingredient. Further, the specification lends support for more than one oral or salivation ingredient in a given region. However, the specification does not support more than one region of an oral comfort region and salivation region respectfully. Therefore the rejection stands.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8, 10-12, 17, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP0407019.

EP discloses a saliva-stimulating center-filled chewing gum. The gum base is made of sugar or sugarless gum. The gum base includes partially hydrogenated vegetable oil/animal fat (9%), monoglycerides, and emulsifiers (lecithin or GMO; see page, 11, lines 2) (8%). See page 3. Sucrose and corn syrup are preferred sugar

bulking agents. See page 11, line 44. The center fill contains sugarless or sugar humectants, thickeners, and 1% flavoring agents. See page 22.

Response to Arguments

Applicant argues that the instant invention requires the salivation agent and oral comforting agent to be concentrated in given regions. It is argued that EP discloses homogenous mixtures of the agents.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out the claims require the oral comfort region to contain a lipid, surfactant, or protein. The examiner points to Table 1 wherein the gum base contains several ingredients including the required lipids and surfactants. Table 5 of EP discloses the liquid center fill contains sugarless humectants and thickeners and 1% flavoring agent. The instant claims require a salivation region that may contain an acidulent, a flavor, cooling compounds, or salt, etc. Further, it is pointed out that each region has open claim language which does not exclude additional ingredients in the respective region.

In regards to the even distribution of the agents, the examiner points out that the agents are in discrete areas. The lipids are contained in the gum base and the center which contains the flavoring agent is also contained in a discrete region. The examiner does note that the hydrogenated oil is mixed homogeneously in the gum base; however the gum base and the center do not mix and occupy different regions. Therefore, it is clear that either agent is "not uniformly distributed in the product" but is concentrated in

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the given region. Note that the method of making the prior art product and the inventive product as described in the specification is the same.

Claims 1-3, 6-8, 10, 13, 15-17, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Bealin-Kelly (6,306,429).

Bealin-Kelly discloses a confectionary composition. The composition contains cooling and warming regions. The liquid, center filled candy drops contain 58.12% sucrose, 41.51% glucose syrup, 0.27% lemon oil, 0.17% menthol, and 0.19% citric acid. The filling contains 84.3% high fructose corn syrup, 15% glycerin, 0.02% lecithin, 0.314%, and 0.16% color. See example 1. The regions are mixed separately and co-extruded.

Response to Arguments

Applicant argues that Bealin-Kelly discloses a confection having a discrete warming and cooling region. However, the applicant argues that the reference does not teach an oral comfort region comprising a surfactant, lipid, or protein. It is further argued that the reference does not teach that lecithin would have an oral comforting property and it is evenly distributed.

Applicant's arguments have been fully considered but they are not persuasive. The claims require two separate regions, one defined as the oral comfort region and the second region referred as the salivation region. The examiner points out that Bealin-Kelly discloses a product with two distinct regions referred to as a warming and cooling region. The examiner points out that a region is not defined by the name an inventor uses but the ingredients contained within the region. Example 1 of Bealin-Kelly

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discloses a product with a candy casing containing peppermint oil, menthol, citric acid, lemon oil, and sucrose. The instant claims require the salivation region to have cooling compounds, i.e. menthol, acidulents, i.e. citric acid, or flavors, i.e. peppermint oil.

Therefore, this requirement is met by the prior art. Bealin-Kelly further discloses a liquid filling center containing high fructose corn syrup, glycerin, lecithin, lemon oil, etc. The instant claims require the oral comfort region to have lipids, i.e. lemon oil, a surfactant, i.e. lecithin, or a protein. Therefore this requirement is met by the reference. It is further pointed out that the reference does not have to state that lecithin will act as an oral comfort agent since this is inherent. In a product claim, the individual role of each ingredient does not hold patentable weight. If the prior art contains the ingredient, it will function similarly *unless* the applicant recites a percentage or some distinguishing property the provides the ingredient with its function.

In regards to the even distribution of the agents, the examiner points out that the agents are in discrete areas. The lecithin is only contained in the liquid center and the citric acid/ menthol is only contained in the outer candy casing. Therefore, it is clear that either agent is "not uniformly distributed in the product" but is concentrated in the given region. Note that the method of making the prior art product and the inventive product as described in the specification is the same.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP0407019 in view of Parnell (4,983,378).

EP discloses a saliva-stimulating center-filled chewing gum. The gum base is made of sugar or sugarless gum. The gum base includes partially hydrogenated vegetable oil/animal fat (9%), monoglycerides, and emulsifiers (lecithin or GMO; see page, 11, lines 2) (8%). See page 3. Sucrose and corn syrup are preferred sugar bulking agents. See page 11, line 44. The center fill can contain various additives such as sweeteners, flavors, medicaments or mixtures. The center fill contains sugarless or sugar humectants, thickeners, and 1% flavoring agents. See page 22. Flavoring agents such as peppermint oil, clove oil, eucalyptus oil, citrus oil, etc. are taught. See page 13. EP states that saliva stimulating gums are known in the art and contain organic acids. See page 2, lines 42-46.

Although, EP discloses a saliva stimulating gum, it does not explicitly disclose the treatment of xerostomia. Further, EP does not exemplify an acid in the center-fill.

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Parnell teaches a method and composition for treating xerostomia. Parnell teaches that xerostoma is a medical condition wherein the flow of saliva is inadequate to provide proper oral hygiene. See column 1, lines 10-15. Further, Parnell teaches the use of a stimulator compound to stimulate salivary gland secretion. Citric acid is taught as the preferred compound. See column 4, lines 43-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of EP and Parnell and utilize EP's composition to treat xerostomia. A skill artisan would be motivated to do so since xerostomia is a condition wherein an inadequate flow of saliva to the mouth exists and EP teaches a saliva stimulating composition; therefore a skilled artisan could reasonably expect treating xerostomia with EP's composition. Further, one would be motivated to look at the teachings of Parnell and incorporate an organic acid into the center-fill since Parnell teaches the use of organic acids stimulate saliva secretion. One would motivated to do so with the expectation of similar results since EP teaches a saliva stimulating composition and teaches the use of medicaments and flavor mixtures in the center-fill.

Response to Arguments

Applicant argues that the claims require separate regions and EP does not teach such a product. It is argued that the secondary reference does not cure this deficiencies.

Applicant's arguments have been fully considered but they are not persuasive. The examiner has already addressed EP's disclosure of separate regions. It is clear that

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a center fill encapsulated by a gum base falls within the scope of separate regions. It should be noted that the applicant has not addressed the combination in regards to the rejection of claim 20 and 21.

Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429).

Bealin-Kelly discloses a confectionary composition. The composition contains cooling and warming regions. The liquid, center filled candy drops contain 58.12% sucrose, 41.51% glucose syrup, 0.27% lemon oil, 0.17% menthol, and 0.19% citric acid. The filling contains 84.3% high fructose corn syrup, 15% glycerin, 0.02% lecithin, 0.314%, and 0.16% color. See example 1. The vesicle-forming agent (lecithin) is taught in the amount of 0.001 to about 1%. See column 5, lines 20-21. The regions are mixed separately and co-extruded.

The reference does not exemplify the instant amount of surfactant/lipid.

It is deemed obvious to one of ordinary skill in the art to look to the teachings of Bealin-Kelly and utilize the surfactant/lipid in the instant amount. One would be motivated to do so since the reference teaches that lecithin may be used in an amount of 0.001 to 1% by weight. Therefore, a skilled artisan could reasonably expect similar results since Bealin-Kelly clearly teaches the suitability of the instant range.

Response to Arguments

Applicant argues that Bealin-Kelly's lecithin is not taught as an oral comforting agent and is used to encapsulate the cooling or warming agent.

Applicant's arguments have been fully considered but they are not persuasive. This argument has been addressed above. Clearly, the center fill contains lecithin and provides for a separate region even if it encapsulates the center fill, it is part of the center fill composition and provides for a distinct region.

New Rejection Based on Amendment

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of Hanke (6,231,900).

Bealin-Kelly discloses a confectionary composition. The composition contains cooling and warming regions. The liquid, center filled candy drops contain 58.12% sucrose, 41.51% glucose syrup, 0.27% lemon oil, 0.17% menthol, and 0.19% citric acid. The filling contains 84.3% high fructose corn syrup, 15% glycerin, 0.02% lecithin, 0.314%, and 0.16% color. See example 1. The regions are mixed separately and co-extruded. The reference teaches that although center filled compositions are preferred, the only criticality of the method of making the product is to provide sequential release wherein the consumer can taste each region distinctly. See column 4, lines 30-50.

The reference does not specify teach a mold for the method of making the product.

Hanke discloses preparation of a confectionary product to relieve cough (note abstract). Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition to provide distinct releases. The flavoring composition contains a gelatin sweetened mixture, 1.4% citric acid solution, colorant, and flavor. The cooling contains a sweetened agent, 0.7% citric acid, and menthol.

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Hanke discloses the use of a mold in which the respective compositions are placed.

(Note example 1)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Bealin-Kelly and Hanke and utilize a mold in the method of making the product. One would be motivated to do so since Hanke also teaches a product with separate regions and utilizes a mold to obtain the desired distinct regions. Therefore, one would be motivated to utilize Hanke's method of making with the expectation of similar results since Hanke's mold would still provide the sequential release required by Bealin-Kelly. Thus the combination yields the instant invention. Further, it is deemed obvious in the confectionary art to make confectionary products with molds since the state of the art at the time the invention was made clearly indicates that the use of molds is known in the confectionary art.

In the absence of showing criticality, it is deemed obvious to one of ordinary skill in the art to manipulate Hanke's mold to further contain a ridge. One would be motivated to do so since Hanke teaches a product having separate and distinct regions, thus adding a ridge to the mold would ensure further separation of the components.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

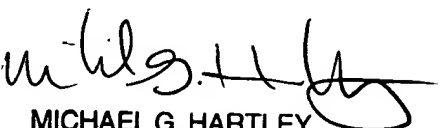
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

January 28, 2004


MICHAEL G. HARTLEY
PRIMARY EXAMINER